Requirements for Tobacco Product Manufacturing Practice

Overview

"This proposed regulation--proposed part 1120 (21 CFR part 1120)--sets forth requirements for tobacco product manufacturing practice (TPMP) and provides a framework for manufacturers of finished or bulk tobacco products to follow that would include:

(1) establishing tobacco product design and development controls to prevent or minimize certain risks;

(2) ensuring that finished and bulk tobacco products are manufactured in conformance with established specifications;

(3) minimizing the likelihood of the manufacture and distribution of nonconforming tobacco products;

(4) requiring investigation and identification of nonconforming products, including those that have been distributed in order to institute appropriate corrective actions, such as conducting a recall as needed;

(5) requiring manufacturers to take appropriate measures to prevent contamination of tobacco products; and

(6) establishing traceability to account for all components or parts, ingredients, additives, and materials, as well as each batch of finished or bulk tobacco product, to aid in investigations of nonconforming tobacco products.

Therefore, this proposed regulation would establish requirements for the control of tobacco product manufacturing activities and the treatment of contaminated or otherwise nonconforming tobacco products, including the investigation, evaluation, and corrective and preventive actions (CAPA) necessary to protect the public health."[1]

[1] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 5, 6

"**This proposed regulation would apply to manufacturers (foreign and domestic) of finished and bulk tobacco products.**"[2]

"The proposed rule would **define "tobacco product manufacturer"** to mean "any person(s), including a repacker or relabeler, who: manufactures, fabricates, assembles, processes, or labels a tobacco product, or imports a finished or bulk tobacco product for sale or distribution in the United States. The manufacture of a tobacco product includes establishing the specifications of or the requirements for a tobacco product."[3]

"As discussed in proposed § 1120.1(a), FDA is proposing TPMP requirements that would apply to manufacturers of all finished and bulk tobacco products that are subject to chapter IX of the FD&C Act (e.g., cigarettes, cigarette tobacco, RYO tobacco, smokeless tobacco, ENDS, eliquids, **pipe tobacco**, **cigars**, hookah tobacco, nicotine gels, and dissolvable tobacco products) but not their related accessories."[4]

"Further, FDA is proposing that foreign manufacturers of finished or bulk tobacco products that are imported or offered for import into the United States be covered under this TPMP rule. (...) FDA believes that covering foreign manufacturers is necessary to assure the protection of the public health. " [5]

"Proposed § 1120.130 provides for an **extended compliance deadline that would grant small tobacco product manufacturers** of finished and bulk tobacco products additional time to implement the requirements in part 1120, consistent with section 906(e)(1)(B)(v) of the FD&C Act. Instead of being required to comply with part 1120 on the effective date of the final rule, s**mall tobacco manufacturers would be required to comply with the requirements** in part 1120 **4 years after the effective date of the final rule.** "[6]

Comment Period:

"FDA is soliciting comment on the scope of the proposed rule, as well as whether the scope of this regulation should be expanded to reach more than finished and bulk tobacco products." [7]

> "If you believe that FDA should expand the scope of this proposed rule to reach additional tobacco products, please explain why you believe FDA should take that approach; which proposed requirements, if any, should apply to other manufacturers;

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[2] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 7
[3] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 7
[4] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 33
[5] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 41
[6] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 210
[7] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 44

whether the regulation should cover manufacturers of all regulated tobacco products, including all components or parts, or only manufacturers of certain products; as well as any public health data and information that would support what you believe would be the appropriate scope of this rule. Alternatively, if you believe that FDA should limit the scope of the proposed regulation, please explain why you believe the scope of the rule should be more limited than finished and bulk tobacco product manufacturers and provide any data or information that would support that such a limited scope would still assure that the public health is protected and that tobacco products are in compliance with chapter IX of the FD&C Act."[8]

"To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the title "Requirements for Tobacco Product Manufacturing Practice." "[9]

Track and Trace

"Proposed § 1120.66(a) would require finished and bulk tobacco product manufacturers to **establish and maintain procedures for their production processes**, including process controls, to ensure that tobacco products conform to requirements established in the MMR in accordance with proposed § 1120.44. **Production processes include the methods, activities, or steps that a tobacco product manufacturer uses to manufacture a tobacco product**. Production processes may include primary processing such as **blending**, casing, and cutting tobacco; **fermenting tobacco;** mixing flavors and liquid nicotine; and **assembling components or parts**."[10]

"Proposed § 1120.70(a) would require finished and bulk tobacco product manufacturers to **establish and maintain procedures to ensure that a production record is prepared for <u>each batch of finished or bulk tobacco products</u>** to demonstrate conformity with the requirements established in the MMR in accordance with § 1120.44."[11]
"Proposed § 1120.70(b)(5) would **require the production record to include all unique identifiers** of all accepted incoming tobacco products, including components or parts, ingredients, additives, and materials, used in the manufacture of the batch of finished or bulk tobacco product."[12]

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[8] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 44, 45
[9] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 238
[10] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 145
[11] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 159
[12] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 161

"The purchasing controls section would require finished and bulk tobacco product manufacturers to establish and maintain procedures for ensuring that purchased or otherwise received products and services related to the manufacture of a finished or bulk tobacco product are from qualified suppliers and conform to established specifications. The acceptance activities section would require finished and bulk tobacco product manufacturers to establish and maintain procedures for incoming and for in-process and/or final acceptance activities, including acceptance criteria, to ensure that products meet established specifications."[13]

"Proposed § 1120.92 **would require finished and bulk tobacco product manufacturers to establish and maintain procedures to control packaging and labeling activities to prevent mixups and to ensure that all packaging and labeling are approved for use by the manufacturer and comply with all requirements** of the MMR (see proposed § 1120.44) as well as all other applicable requirements of the FD&C Act, CSTHEA, FCLAA and their implementing regulations"[14]

"Proposed § 1120.96(a) would require that each finished and bulk tobacco product manufacturer apply a manufacturing code to the packaging or label of all finished and bulk tobacco products. These proposed requirements are generally similar to the practices of manufacturing establishments that follow ISO 9001 and practices that FDA has observed during establishment inspections, as well as to the proposed requirements of the industry recommendations."[15]

"Proposed § 1120.104(c) would require finished and bulk tobacco product manufacturers to **maintain a list of direct accounts. For purposes of this rule, "direct accounts"** means all persons who are customers of the tobacco product manufacturer that receive finished or bulk tobacco products directly from the tobacco product manufacturer or from any person under control of the manufacturer. **Direct accounts may include wholesalers, distributors, and retailers. Direct accounts do not include individual purchasers of tobacco products for personal consumption.**
The list of direct accounts would be required to contain the name, address, and contact information of each entity."[16]

"For example, **tobacco product manufacturers must submit a listing of ingredients, additives, and harmful and potentially harmful constituents** to FDA (...) The proposed TPMP recordkeeping requirements, including the MMR and production record requirements, could help FDA verify that the ingredients of these products are consistent with the listing of ingredients reported to FDA under section 904(a)(1) of the FD&C Act."[17]

Manufacturing Code

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[13] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 9
[14] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 182
[15] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 187, 188
[16] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 198
[17] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 27

"For a finished tobacco product, the **manufacturing code would need to be applied in a manner that assures it would remain on the packaging or label through the expected duration of a consumer's use of the tobacco product**. For a bulk tobacco product, the manufacturing code would need to be applied in a manner that assures it would remain on the packaging or label until receipt by the subsequent tobacco product manufacturer."[18]

"Proposed § 1120.96(b) **would require that the manufacturing code for each** finished and bulk tobacco product be **permanently affixed, legible, conspicuous, and prominent.** The code should be easily visible, and it should not be obscured or be able to be mutilated or removed in whole or in part."[19]

"Proposed § 1120.96(c) would require that the manufacturing code contain the following information listed in the following order: (1) the manufacturing date in two-digit numerical values in the month-day-year format (MMDDYY), and (2) the finished or bulk tobacco product batch number."[20]

"The manufacturing code section would require finished and bulk tobacco product manufacturers to apply a manufacturing code that contains the manufacturing date and batch number to the packaging or label of all finished and bulk tobacco products."[21]

"Unique identifier. We propose to define "unique identifier" as information, such as a code or number, that is maintained for each accepted incoming product that would enable the tobacco product manufacturer and FDA to identify the supplier and unique shipment of the incoming product."[22]

Complaints

"The tobacco product complaints section would require finished and bulk tobacco product manufacturers to establish and **maintain complaint handling procedures** for the receipt, evaluation, investigation, and documentation of all complaints."

"Proposed § 1120.14 sets forth the requirements for the receipt, evaluation, investigation, and documentation of all complaints. FDA considers a "complaint," in this context, to be any communication (including written, electronic, and oral communication) that the tobacco product does not meet expectations, is unsatisfactory or unacceptable, or appears to be a nonconforming product. **Tobacco product complaints may come from any source, including healthcare**

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[18] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 188
[19] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 189
[20] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 189
[21] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 11
[22] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 57

professionals, consumers, the public, and businesses (e.g., retailers, other tobacco product manufacturers)."[23]

"Moreover, even a complaint regarding a side effect that appears to be normally associated with tobacco use may indicate a nonconforming product or a product design issue and, therefore, **would be required to be investigated**."[24]

"Similarly, a complaint about dizziness or nausea could be due to the addition of too many ammonia compounds and other substances to reconstituted tobacco in a cigarette, which can affect free nicotine levels."[25]

> "Proposed § 1120.14(b) would require that personnel evaluate each complaint to determine whether it could be related to:
> (1) a nonconforming tobacco product;
> (2) a product design issue; or
> (3) any adverse experience that is required to be reported under a regulation issued under section 909(a) of the FD&C Act or implementing regulations."[26]

"Accordingly, this proposed section would require that all complaints be processed and evaluated. However, only certain complaints would need to be investigated (i.e., complaints that could be related to a nonconforming product, a product design issue, or reportable adverse experience)."[27]

"When conducting investigations, tobacco product manufacturers should also review available records related to the complaint (e.g., acceptance records, nonconforming product records, or CAPA records)."[28]

"Proposed § 1120.14(e)(1) through (14) states that the complaint record must include the following information, if available: the name of the product, including brand and sub-brand; a description of the product; manufacturing code; date the complaint was received; format of complaint (i.e., oral or written); name, address, and phone number of complainant; nature and details of the complaint, including how the product was used; identification of individual(s) receiving complaint; record of evaluation by the manufacturer, including the name of the individual(s) performing the evaluation; if no investigation is undertaken, the name of the individual(s) responsible for that decision and the rationale for the decision; investigation date(s); record of investigational activities performed and personnel who performed the activities; results of investigation; and any follow up action taken, including any reply to the complainant or any corrective and preventive action taken."[29]

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[23] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 62
[24] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 64
[25] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 64
[26] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 64
[27] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 65
[28] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 68
[29] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 69, 70

Returns

"Proposed § 1120.76(a) **would require each finished and bulk tobacco product manufacturer to establish and maintain procedures for the control and disposition of returned tobacco product. Returned tobacco products are commercially distributed finished or bulk tobacco products returned to the tobacco product manufacturer by any person not under the control of the tobacco product manufacturer, including a wholesaler/distributor, retailer, consumer, or a member of the public.**"[30]

"Proposed § 1120.76(a)(1) would require finished and bulk tobacco product manufacturers to identify returned tobacco product with the product name, manufacturing code, quantity returned, date the manufacturer received the returned product, and reason for return."[31]

Record Keeping

"This provision would **require that the documents and records required to be maintained**, including those not stored at the establishment, be **made readily accessible during the 4-year retention period to FDA for inspection** and photocopying or other means of reproduction. "[32]

"Documents and records required under this section that are associated with a batch of finished or bulk tobacco product must be retained for a period of not less than 4 years from the date of distribution of the batch or until the product reaches its expiration date if one exists, whichever is later."[33]

Exemptions

"Proposed § 1120.140 explains that, under section 906(e)(2) of the FD&C Act, any person subject to any of the TPMP requirements could **petition FDA for a permanent or temporary exemption or variance from any of these requirements.**"[34]

"Proposed § 1120.142 would require that a petition for an exemption or variance be submitted with supporting documentation and contain: (1) the petitioner's name, address, and contact information; (2) **identification of the tobacco product(s);** (3) the requirement(s) in part 1120 for which an exemption or variance is requested; a detailed explanation of why the exemption or variance is requested, including why the tobacco product manufacturer is not able to comply with the requirement(s) of proposed part 1120; and (4) the duration of the proposed exemption or variance."[35]

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[30] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 174
[31] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 175
[32] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 202
[33] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 12
[34] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 211
[35] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 212

"FDA expects that the submission of this information, along with supporting documentation will enable **FDA to determine whether to grant a petition for a variance or exemption**."[36]

"Proposed § 1120.144 explains that FDA may refer any petition submitted under this subpart to the TPSAC. If FDA refers a petition for an exemption or variance to the TPSAC, the TPSAC would be required to report its recommendations to FDA with respect to the petition referred to it within 60 days after the date of the petition's referral. "[37]

FDA can submit to the TPSAC, but does not have to.

"**that FDA would either grant or deny a petition within 60 days after the date the complete petition was submitted to FDA under § 1120.142 or within 60 days after the day after FDA referred the petition to TPSAC**"[38]

"Proposed § 1120.148 explains that after FDA issues an order under § 1120.146, the petitioner would have the opportunity for an informal hearing "[39]

"**Subpart J consists of five sections, and it sets forth the proposed procedures and requirements for petitioning for an exemption or variance from a TPMP requirement.** Pursuant to section 906(e)(2)(B) of the FD&C Act (21 U.S.C. 387f), this subpart also would establish that a petition for an exemption or variance may be referred to the **Tobacco Products Scientific Advisory Committee (TPSAC)** and describe how FDA would make a determination on a petition for an exemption or variance. Finally, pursuant to section 906(e)(2)(E) of the FD&C Act, this subpart would **provide that the petitioner has an opportunity for a hearing after the issuance of an order denying or approving a petition for an exemption or variance.**" [40]

Lab like Environment

"The buildings, facilities, and grounds section would require such manufacturers to ensure that buildings and facilities are of suitable construction, design, and location to facilitate cleaning and sanitation, maintenance, and proper operations. In addition, manufacturers would be required to ensure that facility grounds are maintained in a condition to prevent contamination and to control the water used in the manufacturing process"[41]

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[36] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 213
[37] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 213
[38] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 214
[39] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 214
[40] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 13
[41] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 8

"Proposed § 1120.32 would require finished and bulk tobacco product manufacturers to establish and maintain procedures for the cleanliness, personal practices, and apparel of personnel."[42]

"personnel and the tobacco product manufacturer or the environment would not result in **contamination** of the tobacco product."[43]

"Personnel can contaminate tobacco products by unintentionally transferring bacteria, viruses, or disease through the handling of tobacco products, and contamination (e.g., physical or microbial) may occur at any time during the manufacturing process."[44]

"Examples of such measures for "cleanliness, personal practices, and apparel" **can include outer garment requirements, personal cleanliness, restrictions on jewelry and other loose items**, adequate hand washing before handling a tobacco product, use of gloves, head coverings, or other protective equipment, and daily checks on these practices."[45]

"Proposed § 1120.34(a) would **require finished and bulk tobacco product manufacturers to ensure that any buildings and facilities used in or for the manufacture, packaging, or storage of a tobacco product are of suitable construction, design, and location to facilitate cleaning and sanitation, maintenance, and proper operations**"[46]

"Examples of buildings and facilities that are inadequately constructed, designed or located would include facilities that are constructed of **particle board that have exposed wood chips or flakes that could become a physical hazard**, **facilities that are constructed of porous material and cannot be adequately cleaned and sanitized**, and **buildings and facilities whose equipment is so tightly placed that it prevents adequate cleaning and maintenance of the building or facility**"[47]

"Proposed § 1120.34(a)(1) would **require that buildings and facilities have adequate lighting**. FDA would consider this requirement satisfied if lighting conditions enable the tobacco product manufacturer to perform necessary manufacturing operations, including cleaning, sanitation, and maintenance. Among other things, this requirement is necessary to identify insanitary conditions that may not be visible with inadequate lighting."[48]

"For example, lighting should not attract pests that can contaminate or otherwise render the tobacco products adulterated or misbranded under section 902 or 903 of the FD&C Act. Manufacturers should cover lighting fixtures or use shatter-proof bulbs to prevent tobacco products from becoming contaminated with glass shards if the light bulbs shatter. "[49]

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[42] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 80
[43] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 80
[44] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 80
[45] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 80
[46] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 80
[47] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 81
[48] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 82
[49] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 82

"Proposed § 1120.34(a)(2) **would require that buildings and facilities have adequate heating, ventilation, and cooling (HVAC)**. HVAC equipment and systems are used to maintain the environmental conditions of buildings and facilities."[50]

"Proposed § 1120.34(a)(3) would require finished and bulk tobacco product manufacturers to utilize adequate plumbing (including control of drainage, backflow, sewage, and waste) to avoid being a source of contamination or creating insanitary conditions. For example, water pipes should be designed so condensation does not fall on the tobacco product or tobacco product-contact surfaces, which can cause contamination. In addition, floors cleaned with water (or water-soluble products) should be designed with floor drains to facilitate adequate drainage."[51]

"Proposed § 1120.34(c) would require finished and bulk tobacco product manufacturers to **ensure that water used in the manufacturing process, including water that is or may become part of the tobacco product (e.g., water used as an ingredient or water used on a tobacco productcontact surface) is potable**, will not contaminate the tobacco product, is maintained under positive pressure (e.g., to prevent back siphonage that can draw water from a contaminated source into the water supply system due to leaks or gaps in the mains, cross-connections, or valves), and is supplied from sources that comply with all applicable Federal, State, and local requirements. Water is commonly used in the manufacture of tobacco products, and water that is untreated may be contaminated with Escherichia coli (E. coli) and coliform bacteria"[52]

"Under this proposal, the manufacturer's water supply should come from a source for which adequate controls exist for testing, treatment, and removal of contaminants (e.g., microbes and heavy metals)."[53]

"This proposed requirement would be limited to manufacturing activities and not extend to agricultural activities including growing, cultivation, or curing of raw tobacco"[54]

"This paragraph also would require that the procedures include a **requirement that any pesticide, including rodenticides, insecticides, or fungicides used in the buildings, facilities, and grounds be registered in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act** "[55]

"Proposed § 1120.34(f) would require finished and bulk tobacco product manufacturers to **maintain records of cleaning and sanitation and animal and pest control activities required under this section. These records would be required to include the date and time, the individual performing the activity, the type of activity performed**, any information demonstrating the requirement was met, and any data or calculations necessary to reconstruct the results. We believe these records are necessary for tobacco product manufacturers to ensure that

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[50] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 82
[51] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 83
[52] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 84
[53] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 84
[54] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 86
[55] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 87

the required activities have been conducted and for FDA to verify that the activities have been adequately performed. "[56]

"Proposed § 1120.36(c) would require finished and bulk tobacco product manufacturers to identify (electronically, by signage, or other method of identification), if applicable, all processing lines and major equipment to be used during manufacturing to prevent mixups and contamination. The intent of this identification requirement is to prevent mixups (e.g., flavored vs. nonflavored, regular vs. mentholated) and distribution of nonconforming product. FDA is also proposing that related information (i.e.., which major equipment and processing line was used in the manufacture of a batch of finished or bulk tobacco product) be maintained in the production record, pursuant to proposed § 1120.70(b)(3) to establish traceability and assist with, for example, nonconforming tobacco product investigations. "[57]

"FDA recognizes that it is impractical to identify every piece of equipment used during manufacturing. Thus, the Agency proposes to require identification of major equipment only."[58]

"Proposed § 1120.38(a) would require finished and bulk tobacco product manufacturers to establish and maintain procedures to adequately control environmental conditions where appropriate. In addition, under the proposed requirement, environmental control systems would have to be maintained and monitored to verify that environmental controls, including necessary equipment, are adequate and functioning properly. Environmental control systems include associated equipment (e.g., HVAC equipment, humidifier, air filters) that manages the facility's environmental conditions (e.g., temperature, humidity, ventilation, filtration). These proposed requirements, which are intended to ensure that the tobacco product meets its specifications and is not adversely affected by environmental conditions, complement those in proposed § 1120.34, which are intended, in part, to ensure that buildings and facilities have adequate controls to prevent contamination. These proposed requirements are generally similar to the practices of manufacturing establishments that follow ISO 9001-2015 (Ref. 11)."[59]

Employment Requirements

"Proposed § 1120.12(d) would require finished and bulk tobacco product manufacturers to designate, in writing (on paper or electronically), management with executive responsibility that has the duty, power, and responsibility to implement the proposed requirements under proposed part 1120. Management with executive responsibility refers to those individual(s) who are ultimately responsible for ensuring compliance with proposed part 1120. This responsibility would include the allocation of resources, including facilities, equipment, materials, controls, and personnel used for the manufacture, preproduction design validation, packing, and storage of a tobacco product. These employees are typically senior employees with the authority to establish or make changes to tobacco product

[56] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 87
[57] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 89
[58] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 89
[59] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 93

manufacturing policies and ensure that they are effectively communicated throughout the organization. Management with executive responsibility would be required to establish and maintain required processes and procedures to ensure compliance with requirements under proposed part 1120. Such person(s) also would be required to ensure that TPMP requirements are communicated, understood, implemented, and followed at all levels of the organization. FDA believes that this proposed requirement is generally similar to existing industry practice"[60]

"Proposed § 1120.12(e) would require finished and bulk tobacco product manufacturers to establish and maintain training procedures. This provision would require that training procedures identify training needs and establish training frequency for personnel based on the work the employee performs. "[61]

"Proposed § 1120.12(e) would also require finished and bulk tobacco product manufacturers to train personnel on their assigned responsibility and on the TPMP requirements relevant to their responsibility"[62]

"Proposed § 1120.12(f) establishes the format for training records required by § 1120.12(b). These training records would be required to include the type and description of the training, the training date, the names of the parties performing and taking the training, and documentation supporting completion. Training records should demonstrate which personnel were trained, identify the training completed, and illustrate whether that personnel received the proper training for their job functions. Documentation supporting completion may include the results of an assessment or examination given to personnel upon completion of the training. " [63]

FDA Claims

"Estimated quantified benefits of the proposed rule arise from the value of reduced adverse events due to nonconforming finished and bulk tobacco products and from the reduction of costs associated with reduced product recalls and market withdrawals. We estimate the mean present value of benefits annualized over ten years using a seven and three percent discount rate to be $27.2 million and $29.9 million." [64]

"Initial and recurring costs from this proposed rule arise from conducting tasks associated with establishing and maintaining procedures for various aspects of the manufacturing, preproduction design validation, packing and storage processes. We estimate the mean present value of costs annualized over ten years using a seven and three percent discount rate to be $27.0 million and $28.2 million."[65]

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[60] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 59, 60
[61] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 60
[62] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 60
[63] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 60, 61
[64] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 14
[65] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 15

"A. **Legal Authority** The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was enacted on June 22, 2009, amending the FD&C Act and providing FDA with the authority to regulate tobacco products (Pub. L. No. 111-31). Specifically, section 101(b) of the Tobacco Control Act amended the FD&C Act by adding chapter IX, which provides FDA with the authority to regulate tobacco products and imposes certain obligations on tobacco product manufacturers (including importers), distributors, and retailers."[66]

Pending the courts decision, if Judge Mheta were to decide to vacate the rule, the self reported legal authority, the FDA claims the the Tobacco Control Act gives them the authority to implement this rule. We are currently challenging this law in the court.

"B. Rationale for the Proposed Regulation While all tobacco products have inherent risks to the public health, FDA is proposing TPMP requirements to minimize or prevent product problems, as well as health issues not normally associated with use of a tobacco product."[67]

"Nonconforming products occur for many different reasons, including inadequate sanitation practices, design issues, failures of or problems with purchasing controls, inadequate process controls, improper facilities or equipment, inadequate personnel training, inadequate manufacturing methods and procedures, the introduction or presence of hazards, or improper handling or storage of the tobacco product."[68]

- "Consumers have reported additional substances not ordinarily contained in tobacco products such as biological materials (e.g., mold, mildew, hair, fingernails) and chemical hazards (e.g., ammonia, cleaning agents, and kerosene). Caustic cleaning chemicals may cause vomiting, nausea, allergic reactions, dizziness, numbness, or headaches."[69]

"Further, on June 7, 2017, a group of 13 tobacco companies, a trade coalition representing small tobacco product manufacturers, and a standards organization representing vaping manufacturers and retailers **submitted updated supplemental industry recommendations** in order to provide additional cGMP recommendations for ENDS products."[70]

"**Unlike medical products, tobacco products cannot be "safe and effective" even if used as intended** and, therefore, the FD&C Act requires that marketing applications for tobacco products be evaluated under different standards (see, e.g., the "appropriate for the protection of the public health" standard under section 910 of the FD&C Act)." [71]

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[66] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 16
[67] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 19
[68] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 21
[69] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 22
[70] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 32
[71] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 32

"For finished and bulk tobacco products first commercially marketed or modified after the effective date of this rule, proposed § 1120.42(a)(2) **would require finished and bulk tobacco product manufacturers to perform design verification to confirm that the tobacco product and its packaging meet specifications and design validation to assess the performance of the tobacco product.** These activities would be informed by the risk management process in proposed § 1120.42(a)(1). Process verification and process validation would be separate requirements and are found in proposed § 1120.66. Design verification confirms that the product and packaging meet their specifications. "[72]

"Proposed § 1120.62(c) would also require that records maintained under this section include a written agreement (e.g., purchase order, contractual agreement) that the supplier will notify the manufacturer of any change in the product or service so that the manufacturer can determine whether the change may affect the specifications of the finished or bulk tobacco product established in accordance with § 1120.44(a)(1)."

"The finished or bulk tobacco product manufacturer would have the ultimate responsibility for ensuring that all applicable requirements under proposed part 1120 are met."

Economic Impact

"Furthermore, we estimate that, if the proposed rule is finalized, the costs of product recalls and market withdrawals may fall by between $4 million and $213 million per year."[73]

"Examples of these tasks include conducting new or more stringent manufacturing activities, writing and updating standard operating procedures (SOPs), training employees to engage in new or more stringent manufacturing activities, and keeping new or additional records. We estimate that (undiscounted) one-time costs range from $39 million to $73 million and (undiscounted) recurring costs range from $15 million per year to $56 million per year."[74]

"We therefore estimate the present value of total domestic costs annualized over ten years using a discount rate of seven percent is estimated to range from $13 million per year to $54 million per year, and from $14 million per year to $43 million per year using a discount rate of three percent. Our estimated benefits will begin to accrue on the same years as the compliance dates (years 2 and 6). The present value of total benefits annualized over ten years using a discount rate of seven percent is estimated to range from $1.9 million per year to $97.0 million per year, and from $2.1 million per year to $106.5 million per year using a discount rate of three percent. Table 1 summarizes our estimate of the annualized costs and benefits of the proposed rule."[75]

Environmental Impact

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[72] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 110
[73] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 218
[74] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 220
[75] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 220, 221

"**The proposed action is not anticipated to pose the potential for serious harm to the environment or to adversely affect a species or the critical habitat of a species** described in § 25.21(b). Thus, FDA has determined that no extraordinary circumstances exist that would require preparation of an EA or an EIS. "[76]

… But will require extreme renovations to the grounds, factories and facilities to be in compliance. These facilities are typically remote and would require large equipment to be brought far from large cities. There will be an environmental impact of this. paired with this, large industrial HVAC units will require different electric delivery and production then is currently required. leading to an increase in carbon footprint, in very rural areas.

Other Requirements

"For example, for a **released product found to be nonconforming because of its nicotine concentration**, under the proposed rule, the manufacturer and/or FDA could review the MMR and the purchasing, acceptance activities, and production records to determine the nicotine concentration of the released product as well as who conducted the testing and signed off on the release of the product."[77]

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"**The proposed rule would not apply to manufacturers of accessories** of finished or bulk tobacco products. **FDA proposes to define an "accessory" as any product that is intended or reasonably expected to be used with or for the human consumption** of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following: (1) **is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product or** (2) is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but (i) solely controls moisture and/or temperature of a stored tobacco product; or (ii) solely provides an external heat source to initiate but not maintain combustion of a tobacco product."

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"Proposed § 1120.42(a)(1)(i) would require **each** finished and bulk tobacco product manufacturer to identify all known or reasonably foreseeable risks associated with the tobacco product and its package, as well as its production process, packing, and storage."[78]

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[76] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 239
[77] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 32
[78] HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule., 99

Rundowns:

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Footnote: HHS, FDA, Requirements for Tobacco Product Manufacturing Practice, Proposed Rule.,

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DEPARTMENT OF HEALTH AND HUMAN SERVICES, Food and Drug Administration 21 CFR Part 1120 [Docket No. FDA-2013-N-0227] RIN 0910-AH91, Requirements for Tobacco Product Manufacturing Practice AGENCY: Food and Drug Administration, Health and Human Services (HHS). ACTION: Proposed rule.